MAR 18 1982

493-6-12 EP 5.1: M27

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

February 1982

EPA

Magnesium Phosphide

COMPLETED

168

Pesticide Registration Standard

EP 5.17

Acknowledgements

I. Special Pesticide Review Division (SPRD)

David Brooks	Project Manager

II. Support Team

A. Hazard Evaluation Division (HED)

Ed Brittin	Residue Chemist
Stan Gross	Toxicologist
William Burnam	Supervisory Toxicologist
Robert Holst	Plant Physiologist
Harry Craven	Aquatic Biologist
Russel Farringer	Wildlife Biologist
Hudson Boyd	Environmental Chemist

B. Benefits and Field Studies Division (BFSD)

William Gross	Entomologist
Roger Holtorf	Economist
E. David Thomas	Supervisory Entomologist, Section Head

C. Registration Division

Lachman Bhatia	Product Manager
William Miller	Supervisory Product Manager

III. Special Acknowledgement

A. Special Pesticide Review Division (SPRD)

Paul Lapsley	Branch Chief
Joan Warshawsky	Section Head
Paul Parsons	Project Manager
Barbara Moore	Secretary
Tonda Hicks	Clerk Typist

B. Hazard Evaluation Division (HED)

Ken Bailey	Scientific Policy Staff
Julian Donoso	Residue Chemist
Nancy Dodd	Residue Chemist
Norma Whetzel	Residue Chemist

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I. How to Register Under a Registration Standard

A. Organization of the Standard

The first part of this document explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second part presents the Agency's regulatory position and rationale. The third part sets forth the requirements, in tabular form, that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining parts, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

B. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks associated with the use of the proposed pesticide. However, the established approach to making these findings has been found to be defective on two counts.

First, the Environmental Protection Agency (EPA) and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product-by-product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product-by-product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even possible that materials may have been lost from the data files.

When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978) and in 1980 (45 FR 72948, November 3, 1980), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [see FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product-by-product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have; compliance with standards of toxicity, composition, labeling, and packaging; and satisfaction of the compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly designed label precautions are strictly followed. Thus, the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticides safely, responsibly, and in accordance with label directions. A restricted use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use", or not classified at all, is available for use by any individual who is in compliance with State and local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in Part II of this Standard.

C. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute such product in commerce, must apply for reregistration. This application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies, if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

D. "Product-Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Ecological Effects and Residue Chemistry. These determinations are based primarily on the data Guidelines proposed in 1978 (43 FR 29686, July 10, 1978, and 43 FR 37336, August 22, 1978), and in 1980 (45 FR 72948, November 3, 1980), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement were actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which the Agency has found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaulation of other products, depending upon the composition, formulation type, and intended use of the product in question. The Standard states which data requirements apply to which product use categories (see Part III).

The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1) data that are "product-specific," i.e., data that relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

2) "generic" data that pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use.

The Agency requires certain "product-specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product-specific" data on any product other than the applicant's are irrelevant, unless the other product is similar in composition to the applicant's. (Where it has been found practical to group similar products for purposes of evaluating, the Standard indicates guideline requirements that support similar products.) "Product-specific" data on the efficacy of particular end-use products are also required where the formulation may affect public health or where failure of efficacy could cause public health problems (see 44 FR 27932, May 11, 1979).

All other data needed to evaluate pesticide products concern the properties or effects of a particular ingredient (normally a pesticidally active ingredient, but in some cases a pesticidally inactive or "inert" ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient, e.g., the acute LD_{50} of the active ingredient in the technical or purest grade (see proposed 40 CFR 163.81-1(a), 43 FR 37355).

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally would be used to make an end-use, food crop pesticide. However, if an end-use product's label specified that it was for use only in ways that did not involve a food/feed exposure or repeated human exposure via the oral route, then the subchronic oral study would not be relevant to the evaluation of the manufacturing-use product.

If a registrant of a currently registered end-use product wishes to avoid the costs of data compensation under FIFRA Section 3(c)(1)(D) or data generation under Section 3(c)(2)(B) for "generic" data that are required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his products. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

E. Data Compensation Requirements Under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. Compensation must be offered for all data which are described by all the following criteria:

1) the data were first submitted to EPA or to its predecessor agency, USDA, or FDA on or after January 1, 1970;

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2) the data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit or a tolerance, an amendment adding a new use to a registration, or for reregistration, or to support or maintain in effect an existing registration;

3) the data are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product composition and intended use pattern(s);

4) the data are determined by EPA to be valid and usable in reaching regulatory conclusions; and

5) the data are not those for which the applicant has been exempted by FIFRA Section 3(a)(2)(D) from the study to offer to pay compensation. (This exemption applies to the "generic" product, not to "product-specific" data. The exemption is available only to an applicant whose end-use product is formulated from another registered manufacturing-use product containing that active ingredient.)

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D). An applicant would never be required to offer to pay for "product-specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product; that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where, because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product-specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(c)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements. This is with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

F. Obtaining Data to Fill Data Gaps; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have not been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registration oriented decisions) and have not been located in the published literature search that EPA conducted in preparation of this Standard. Such instances of missing but required data are referred to in this Standard as "data gaps."

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies, to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a Section 3(c)(2)(B) order, his product registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in Part III, the "generic" data gaps and "product-specific" data gaps for end-use products. It also notes the classes of products to which these data gaps pertain. The Standard also points out that to be registered under the Standard, a product must be supported by certain required "product-specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product-specific" data gaps on a "product-by-product" basis. (The Standard will, in some cases, note which data EPA possesses that would suffice to satisfy certain "product-specific" data requirements for a category of products with similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue FIFRA Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps, whether "product-specific" or "generic" data gaps. The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

In addition, FIFRA Section 6(a)(2) requires the registrant to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. The registrant should notify the Agency of interim results of studies in progress, if those results show possible adverse effects.

G. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the Part II.C. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies may be requested from the Agency. When all of the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and reissued for publication.

While Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be indicated in the Guidance Package.

II. Regulatory Position

A. Introduction

This Part presents the Agency's regulatory position and rationale based on an evaluation of all registered products containing magnesium phosphide as the sole active ingredient with the same use patterns described in this Standard. After briefly describing the chemical, this Part presents the regulatory position and rationale, the criteria by which applications for registration of magnesium phosphide products will be approved, additional labeling considerations and requirements related to the tolerance reassessment, if applicable. A summary of the data requirements is contained in Part III. Discussion of the data upon which this regulatory position is based is presented in each of the disciplinary chapters, Parts IV through VIII.

B. Description of Chemical

Magnesium phosphide is a restricted use, nondomestic fumigant, for use only by certified applicators for the control of insects in raw agricultural commodities, processed foods and animal feeds, and other nonfood/nonfeed commodities (including tobacco). Magnesium phosphide is also registered for the control of burrowing rodents in noncrop areas. Although magnesium phosphide is the registered active ingredient for this pesticide, phosphine gas, which is liberated in the presence of moisture, actually performs the fumigant action for this pesticide. The American Chemical Society's Chemical Abstracts Service (CAS) number for magnesium phosphide is 12057-74-8 and the EPA Shaughnessy number is 066504. Currently, there are no technical or manufacturing-use products registered with the Agency. Magnesium phosphide end-use products are produced in an intergrated-formulation system. That is, the technical material is formulated directly into an end-use product.

C. Regulatory Position

Magnesium phosphide, as decribed in this Standard, may be registered for sale, distribution, and use in the United States. The Agency has considered the limited amount of scientific data concerning magnesium phosphide and phosphine obtained from the open literature as of October, 1981, and the data submitted to the Agency by the registrants through the time of publication of this Standard (February, 1982). Based on review of these limited data, the Agency finds that none of the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations (CFR) were met or exceeded for magnesium phosphide and that it does not appear to cause unreasonable adverse effects when applied in accordance with proper label directions and precautions. Magnesium phosphide products currently registered may be reregistered subject to the conditions imposed for data requirements. New products may be registered under this Standard and are subject to the same requirements. Revised label requirements will be addressed in the Guidance Package which accompanies this Standard and any special label requirements for this pesticide will also be discribed in Part II.E of this Standard (see 40 CFR 162.10 for a detailed description of standard labeling requirements).

D. Regulatory Rationale

A review of the available data regarding the end-use products of magnesium phosphide and its principle active agent, phosphine, shows that much information that could be used to support registration and reregistration is not available. The Agency has the prerogative not only to request information to satisfy the data Guidelines proposed in 1978 and 1980, but may also require additional testing. These additional tests may be requested by the Agency if it believes that particular concerns regarding the health or environmental effects of a pesticide must be evaluated. In some cases, this additional testing may be deferred pending the Agency's review of specific test protocols developed by the registrant or the completion of other related tests the Agency requires for registration of a product (e.g., tiered testing).

It is the policy of the Agency not to automatically request guideline information just because a particular guideline exists. Each element of the guideline is considered individually with regard to the pesticide's uses, exposure and risk. If the Agency concludes that specific elements of the data guidelines are required to prepare a comprehensive Registration Standard, the data will be requested.

The Agency has concluded that it should continue registration for this product for the following reasons:

1) Because phosphine gas has a high acute inhalation toxicity, the insecticide uses of magnesium phosphide are restricted to certified applicators who are required to wear protective clothing and a respirator during the application process. Certified applicators are also required to wear protective clothing (e.g., gloves) when applying magnesium phosphide as a rodenticide. Consequently, the Agency does not believe the use of this pesticide presents any unreasonable acute risk when used in accordance with label instructions.

2) No significant chronic adverse effects have been uncovered in the review of studies pertinent to magnesium phosphide or phosphine. These studies include some which, while failing to meet guideline requirements, provide a level of qualitative information. As a result of examining these studies, the Agency has concluded that there is no immediate cause for regulatory concern regarding the chronic effects of magnesium phosphide or phosphine gas.

3) In accordance with FIFRA, the Agency does not routinely cancel the registration of products or withhold registration merely for the lack of data (see Sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, the publication of this Standard provides a mechanism for identifying data needs, and registration of magnesium phosphide under this Standard allows for the improvement of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency and the registerability of the chemical will be reassessed.

4) If the label instructions are followed, applicators should not be exposed to measurable levels of the pesticide during the fumigation of commodities. However, reentry data are being required to evaluate more precisely the air concentrations of phosphine in fumigation facilities, if any, following the fumigation process.

5) The Agency has required label revisions for the rodenticide fumigant products which will eliminate potential hazards to nontarget organisms.

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Because of the unique properties of this pesticide and the restrictions on its use, the Agency is waiving or reserving some data requirements for magnesium phosphide or phosphine for the following reasons:

1) The label requires the application site to be airtight and capable of containing the liberated phosphine gas. Consequently, there should be no exposure to the applicator or others who live or work in the immediate fumigation area. When aerating the application site after fumigation, the label also requires the applicator to wear protective equipment (e.g., respirator) when testing the site to certify that phosphine gas has been reduced to levels safe for reentry. The current reentry level, 0.3 ppm, is based on acute and subchronic inhalation studies for phosphine gas established through the Occupational Safety and Health Administration's (OSHA) Permissible Exposure Level (PEL). It is possible that this level may not protect the applicator from other chronic adverse effects. However, the post-fumigation atmosphere theoretically should decrease to some concentration approaching zero as the site is further aerated. Thus, the Agency will hold in abeyance further testing for teratology, mutagenicity, and subchronic inhalation until the Agency receives and reviews the requested environmental reentry data to determine the exposure, if any, to the applicator. If there is significant exposure to the applicator based on this review, the existing PEL may not be adequate to protect applicators reentering magnesium phosphide-treated storage areas from other chronic adverse effects and the Agency may require these studies.

2) Three types of tolerances have been established for magnesium phosphide for the amount of phosphine in or on commodities: 1) 0.1 ppm on raw agricultural commodities (40 CFR Section 180.375); 2) 0.01 ppm on processed foods (21 CFR Section 193.255); and 3) 0.1 ppm on animal feed (21 CFR Section 561.268). The tolerance of 0.1 ppm is being allowed for raw agricultural commodities since residual phosphine will probably dissipate from the commodity or will be converted to oxy-acids of phosphorus which the Agency has determined to be toxicologically insignificant. Any unreacted magnesium phosphide which might remain if the formulations are added to the commodity is expected to be converted to minute amounts of phosphine gas which is readily dissipated from the commodity upon further aeration. However, radiolabeled phosphorus studies (see Part VI, Residue Chemistry) indicate that a substantial portion (about 30%) of the phosphine conversion products have not been identified. Thus the Agency will hold in abeyance requirements for chronic feeding, oncogenicity, metabolism, and reproductive studies until these unidentified residues are identified. If the Agency concludes, when these residues are chemically characterized, that they are toxicologically insignificant, the requirement for chronic feeding, oncogenic, metabolism, and reproduction studies will be waived.

3) The results of the literature review indicated potential phosphine residues at levels below the established tolerance on processed foods and animal feed. Although there are no data establishing the fate of such minute residues, phosphine oxidizes readily to the relatively innocuous oxy-acids of phosphorus. Consequently, the Agency has reserved the requirements for animal metabolism data and data on storage stability of the sample until the unidentified residues are identified. If the Agency cannot determine that these unidentified residues are toxicologically insignificant, the Agency may require the animal metabolism and storage stability data.

4) The Agency has considered any product containing magnesium phosphide to be as highly toxic as the phosphine gas which is liberated from magnesium phosphide and has placed these products in Toxicity Category I for labeling purposes based on acute and subchronic inhalation studies. The usual toxicity studies to rate magnesium phosphide products for other categories based on dermal, eye, or oral effects appear unwarranted. Thus, the Agency is waiving all of the acute toxicity studies for all magnesium phosphide products.

5) The Agency has previously requested that environmental fate data and residue data for phosphine be generated to support the registration/reregistration of products containing aluminum phosphide under the Aluminum Phosphide Registration Standard (EPA, 1981). Because both magnesium phosphide and aluminum phosphide generates the same toxic agent, phosphine, and both pesticides have similar use patterns, the generic data requirements (see Tables III.A-1 through 4) are identical. Therefore the Agency will accept the generic data currently being developed under the Aluminum Phosphide Registration Standard to support the registration/reregistration for products containing magnesium phosphide.

E. Criteria for Registration Under the Standard

To be subject to this Standard, magnesium phosphide products must meet the following conditions:

- contain magnesium phosphide as the sole active ingredient which generates the fumigant, phosphine, and have the same use patterns described in this Standard;
- bear required labeling; and
- conform to the acute toxicity limits, product composition, and use pattern requirements stated below.

The applicant for registration or reregistration of magnesium phosphide products subject to this Standard must comply with all terms and conditions described in this Standard, including a commitment to fill data gaps on a time schedule specified by the Agency as indicated in the Guidance Package and, when applicable, offer to pay compensation to the extent required by Sections 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136a(c)(1)(D). As discussed in Part I and in the Guidance Package, applicants for registration of magnesium phosphide products under this Standard must contact the Agency for specific instructions, including updated information on data requirements, and contact companies whose data may be cited and to whom compensation must be offered.

1. Manufacturing-Use Magnesium Phosphide Products

Although there are no manufacturing-use magnesium phosphide products registered with the Agency, the Agency would consider registration of these products as indicated below:

a. Acceptable Ranges and Limits

i. Product Composition Range

To be covered under this Standard, manufacturing-use magnesium phosphide products must conform to the requirements stated below:

Active Ingredient: Any percentage acceptable.

ii. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use magnesium phosphide products in the toxicity categories indicated by a "yes:"

	I	II	III	IV
Acute oral toxicity	yes	yes	yes	yes
Acute dermal toxicity	yes	yes	yes	yes
Acute inhalation toxicity	yes	yes	yes	yes
Primary eye irritation	yes	yes	yes	yes
Primary dermal irritation	yes	yes	yes	yes

iii. Use Patterns

To be covered under this Standard, manufacturing-use magnesium phosphide products must be labeled to allow for formulation into end-use fumigants which are intended only for one or a combination of the following use patterns:

1) Food/Feed, Nondomestic, Indoor Use (raw agricultural commodities)
2) Food/Feed, Nondomestic, Indoor Use (animal feed)
3) Food/Feed, Nondomestic, Indoor Use (processed commodities)
4) Nonfood/Nonfeed, Nondomestic, Indoor Use (including tobacco)
5) Nonfood/Nonfeed, Nondomestic, Outdoor Use (rodent control)

iv. Required Labeling

All manufacturing-use magnesium phosphide products must bear appropriate labeling as specified in 40 CFR 161.10. The Agency may, after review of data to be submitted under this Standard, impose additional labeling requirements.

2. End-Use Magnesium Phosphide Products

a. Acceptable Ranges and Limits

i. Product Composition Range

To be covered under this Standard, end-use magnesium phosphide products must conform to the requirements stated below:

Active Ingredient:	Any percentage acceptable.
Inert Ingredient:	Only those inert ingredients which are exempt from the requirements of a tolerance [see 40 CFR Section 180.1001 (c)] are acceptable as ingredients in products which are mixed directly with commodities. However, for those products registered only as "space fumigants" (i.e., products such as the "Fumicel" which are not mixed with commodities), the formulating inerts need not be exempted. The "Fumicel" products do contain inerts which are not cleared and cannot be currently mixed directly with commodities.

ii. Acute Toxicity Limits

Because the fumigant in this pesticide is acutely toxic, all uses are restricted to certified applicators. The Agency will consider registration of end-use magnesium phosphide products in the toxicity categories indicated by a "yes:"

	I	II	III	IV
Acute oral toxicity	yes	yes	yes	yes
Acute dermal toxicity	yes	yes	yes	yes
Acute inhalation toxicity	yes	yes	yes	yes
Primary eye irritation	yes	yes	yes	yes
Primary dermal irritation	yes	yes	yes	yes

iii. Use Patterns

To be covered under this Standard, end-use magnesium phosphide products formulated as discs, plates, pellets, or tablets must be labeled as a fumigant for one or more of the following uses*:

1) Food/Feed, Nondomestic, Indoor Use (raw agricultural commodities)
2) Food/Feed, Nondomestic, Indoor Use (animal feed)
3) Food/Feed, Nondomestic, Indoor Use (processed commodities)
4) Nonfood/Nonfeed, Nondomestic, Indoor Use (including tobacco)
5) Nonfood/Nonfeed, Nondomestic, Outdoor Use (rodent control)

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* A comprehensive description of application rates, sites, pests and limitations that the Agency has accepted can be found in the EPA Index to Pesticide Chemicals-Magnesium Phosphide (EPA, 1981).

iv. Required Labeling

All magnesium phosphide end-use products must bear appropriate labeling as specified in 40 CFR 161.10*. The Agency may, after review of data to be submitted under this Standard, impose additional labeling requirements. Currently, all registered magnesium phosphide products contain adequate specialized labeling statements regarding the use of protective clothing, appropriate application rates, notification of appropriate authorities when applying the product, and safe disposal of spent magnesium phosphide residues. Currently registered products display many specialized labeling precautions. For those uses indicated, the following label statements are required:

Product Chemistry Statements

The following physical or chemical hazards, and storage and disposal statements must appear on the label:

Physical or Chemical Hazards

> "Keep away from liquid or water as this causes immediate release of gas. Piling of tablets or the dust from their decomposition may cause a temperature increase and a flash could occur. Protect from moisture, open flames or heat."

Storage and Disposal

> "Store only in cool, dry locked, and ventilated room. Protect from moisture, open flames or heat. Dispose of containers by flushing several times with water, crush and bury."

Residue Chemistry Statements

For those magnesium phosphide end-use products for use on foods and feeds, the following statements concerning aeration of the fumigated commodity must continue to appear on the labeling to prevent the established tolerances from being exceeded:

> "Fumigated foods and feeds shall be aerated for at least two days (48 hours)."

> "Tobacco, when fumigated in warehouse or under tarpaulin, shall be aerated for at least two days (48 hours), but when fumigated in hogsheads the aeration time shall be at least 72 hours."

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* The magnesium phosphide products should also conform to the June 5, 1980 *Federal Register* notice (45 FR 37884) announcing the initiation of the Label Improvement Program. On December 4, 1980, the Office of Pesticide Programs, EPA, requested that registrants having registered products containing magnesium phosphide modify their labels if the product has use directions for the fumigation of boxcars, hopper cars, railroad cars, vans, trailers, trucks, structures, warehouses, food processing plants, barges or on shipboard (in transit or shiphold). The labels of the currently registered products containing magnesium phosphide have been updated to the Agency's labeling requirements.

Because magnesium phosphide end-use products must not be added directly to processed foods during the fumigation process, the following precautionary statements must continue to appear on the labeling to prevent contamination of these commodities:

> "Under no condition should any processed food, feed or tobacco be permitted to come into contact with magnesium phosphide or with the residues of spent magnesium phosphide except when added directly to processed brewer's rice, malt, and corn grits stored by breweries for use in the manufacturing of beer."

The following statements must continue to appear on the labeling where magnesium phosphide pellets or tablets are used with moisture permeable envelopes to ensure proper disposal of the pesticide and to preclude phosphine exposure to commodity retailers:

> "When pellets (or tablets) of magnesium phosphide are placed in moisture permeable envelopes, the envelopes shall be fastened to a substantial support; place no more than 10 pellets (no more than 2 tablets) into one envelope."

> "Magnesium phosphide shall not be placed in or attached to packages or cartons intended for retailers."

Ecological Effects Statements

The Environmental Hazards section of the labeling for rodenticide uses of magnesium phosphide must include the following statement:

> "This product is highly toxic to wildlife and fish. All burrows should be checked for signs of nontarget animals and if they are present, burrows should not be treated."

Because the rodenticide use of magnesium phosphide end-use products may be hazardous to a number of nontarget mammalian, avian, and reptilian species, the following statements must appear in the precautionary section of the labeling under the heading "Endangered Species Consideration:"

1) Black-Footed Ferret:

> "Do not use this product in the range of the Black-footed ferret. Contact the nearest U.S. Fish and Wildlife Service Office (Endangered Species Specialist) before the product is used. They will arrange for a ferret survey of the proposed use site."

2) Utah Prairie Dog:

> The directions for use for controlling prairie dogs must include the following restriction: "except Utah prairie dogs."

3) San Joaquin Kit Fox:

> "This pesticide should not be used within 1 mile of active dens of the San Joaquin kit fox in the following California counties: Kern, Kings, Fresno, San Luis Obispo, Merced, Monterey, Santa Barbara, Ventura, Tulare, and San Benito. Prior to use, contact the California Department of Fish and Game for recommendations."

4) Blunt-Nosed Leopard Lizard:

> "This pesticide should not be used in the range of the Blunt-nosed leopard lizard in the following California counties: Kern, Fresno, Kings, Madera, Merced, and Tulare. Prior to use, contact the California Department of Fish and Game for recommendations."

5) Eastern Indigo Snake:

> "Do not use this product in the range of the Eastern Indigo snake in the following states: Mississippi, Alabama, South Carolina, Georgia, and Florida."

6) Desert Tortoise:

> "This pesticide should not be used in the critical habitat of the Beaver Dam slope population of the Desert tortoise in Utah. This comprises an area extending from the southwest facing slope of the Beaver Dam Mountains, across Highway 91, west along the Arizona border and 10 miles to the Nevada border."

Toxicology Statements

Because the labeling for the currently registered end-use products contains sufficient specialized precautionary statements regarding complete application procedures, the use of protective clothing and respirator, and updated precautions required for magnesium phosphide under the Agency's Label Improvement Program, the labeling of the various magnesium phosphide end-use formulations should continue to include the following statements for all uses:

"RESTRICTED USE PESTICIDE"

> "For retail sale to and use only by certified applicators or persons under their direct supervision and only those uses covered by the certified applicator's certification."
>
> "Not for use or storage in or around inhabited areas."

F. Tolerance Reassessment

1. Tolerances in the United States

The tolerances established for magnesium phosphide in or on raw agricultural commodities (40 CFR Section 180.375) for residues of the fumigant, phosphine, are as follows:

Commodity*	Residue in ppm
Almonds	0.1
Barley	0.1
Beans, cocoa	0.1
Beans, coffee	0.1
Cashews	0.1
Corn	0.1
Corn, pop	0.1
Cottonseed	0.1
Dates	0.1
Filberts	0.1
Millet	0.1
Nuts, Brazil	0.1
Nut, pistachios	0.1
Oats	0.1
Peanuts	0.1
Pecans	0.1
Rice	0.1
Rye	0.1
Sorghum	0.1
Soybeans	0.1
Sunflower, seed	0.1
Walnuts	0.1
Wheat	0.1

Tolerances have been established for magnesium phosphide in processed foods (21 CFR Section 193.225) and animal feeds (21 CFR Section 561.268) for residues of the fumigant, phosphine. Such residues may not exceed 0.01 ppm on processed foods and 0.1 ppm on animal feed.

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* Sufficient data have been submitted to established 0.1 ppm as the crop-group tolerance for both grain crops and nuts. The terms "grain crops" and "nuts" include crops in addition to those listed above [see 40 CFR 180.34(f)].

2. Canadian and CODEX Tolerances

Although not officially accepted, CODEX has recommended phosphine tolerances as follows:

Commodity	Residue in ppm
Cereals, raw	0.1
Cocoa beans*	0.01
Nuts*, raw	0.01
Peanuts*, raw	0.01
Breakfast cereals	0.01
Flour and other milled products	0.01
Dried foods	0.01
Dried fruit	0.01
Dried vegetables	0.01
Spices	0.01

In Canada, residues of phosphine >0.1 ppm are not permitted in raw cereals, soybeans, processed food, or animal feeds.

As noted in Section VII.B of this Standard on metabolism, studies reviewed for the Aluminum Phosphide Registration Standard (EPA, 1981) show that under typical fumigation conditions, phosphine reacts irreversibly with raw agricultural commodities and probably with most processed foods and feeds. These data also indicate these irreversibly bound residues are quantitatively dependent upon the conditions of fumigation. Under conditions typical to the fumigation of wheat, such residues ranged in amount from about 3-5 ppm. These residues have been partly (about 70%) identified as the oxy-acids of phosphorus (phosphoric, phosphorus, and hypophosphorus) which the Agency considers toxicologically insignificant. The identity of the remaining residue (about 30% of the total) constitutes a significant data gap for this Standard and the Aluminum Phosphide Registration Standards for the reassessment of the tolerances established for magnesium phosphide. Data which would resolve this data gap for both Standards were requested in the Aluminum Phosphide Registration Standard (EPA, 1981).

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* Except for these three items and the more extensive list of items (raw agricultural commodities and processed foods) for which tolerances have been established in the United States, the tolerances being considered for adoption by CODEX and those of this country are in agreement. Data reviewed for the Aluminum Phosphide Registration Standard indicate that should CODEX officially accept these tolerances, the currently accepted treatment of these three items by directly mixing with products of aluminum and magnesium phosphide would cause residues (consisting of phosphine per se, unidentified reaction products of phosphine with fumigated commodity and product non-volatiles impregnated with unreacted phoshide) which would exceed the 0.01 ppm CODEX tolerance.

III. Summary of Data Requirements

A. Introduction

Applicants for registration of end-use magnesium phosphide products must cite or submit the information identified as required in the tables in this Part. The tables applicable to end-use products indicate whether the product to be tested is the technical grade or the formulation. Data generated on one formulation may be used to satisfy the data requirement for a substantially similar formulation, based on the chemical composition as indicated by the Confidential Statement of Formula (CSF). Information on which product-specific data requirements are already satisfied is available in the Guidance Package and in Table III.B and C of this Standard.

Preceding each requirement, with the exception of Residue Chemistry, are listed the Proposed Guidelines which describe the type of data and when the data are required to be submitted. Justification for the test requirement is provided in the Guidelines (see 43 FR 29696 of July 10, 1978 and 43 FR 37336 of August 22, 1978). A discussion of why data additional to that already specified in the Guidelines are necessary, or why data usually required are not necessary for this chemical, is explained in footnotes to the tables. Areas where additional data may be required as the result of tiered testing are indicated.

Bibliographic citations in the following tables indicate that the study listed accomplishes one of the following:

1) provides all the information required by the guideline requirement; or
2) provides partial information required by the guideline requirement which is elaborated on by an accompanying footnote.

The word "yes" under the heading "Does EPA have data to partially or totally satisfy this requirement?" means that the requirement has been fully satisfied, unless otherwise noted.

The Agency requires the submission of residue and environmental fate data requested in Tables III.A-2 and 4 of this Standard to support the registration/reregistration of products containing aluminum phosphide under the Aluminum Phosphide Registration Standard (EPA, 1981). Because both aluminum phosphide and magnesium phosphide generate the same toxic agent, phosphine, and both pesticides have similar use patterns, the generic data requirements for these two chemicals are identical. Thus, the Agency will accept generic data developed under the Aluminum Phosphide Registration Standard to support the registration/reregistration of products containing magnesium phosphide.

B. Generic Data Requirements, Table III.A

This table discusses those data that pertain to the properties or effects of magnesium phosphide as an active ingredient. Thus, these data are relevant to an evaluation of the risks of all products containing magnesium phosphide. Providing data to fill generic data requirements is generally the responsibility of the registrant(s) of manufacturing-use magnesium phosphide products. However, because there are no manufacturing-use products registered, the registrants of end-use magnesium phosphide products must assume this responsibility.

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Registrants of end-use products containing magnesium phosphide are advised that if the Agency does not receive commitments to fill data gaps identified in Table III. A within 90 days of issuance the Guidance Package, the end-use product registrations may be suspended.

Applicants for registration or reregistration of end-use magnesium phosphide products must acknowledge reliance on existing data which fill indicated data requirements under FIFRA Section 3(c)(1)(D). These data are listed under the column "Bibliographic Citation" in Table III.A.

C. Product-Specific Data Requirements for Manufacturing-Use, Table III.B, and End-Use Magnesium Phosphide Products, Table III.C

These tables discuss those data that relate only to the properties or effects of a product with a specific composition (or substantially similar composition). Thus, these data are required of each formulation (or substantially similar product) to characterize the product's particular composition and physical/chemical properties, and to characterize the product's acute toxicity. Providing data to fulfill these requirements is the responsibility of each applicant for the registration or reregistration of a manufacturing-use or an end-use magnesium phosphide product. If the Agency has data which fulfill this requirement for a particular product(s), this is indicated in the table and in the Guidance Package accompanying this Standard.

Product-specific data may be acknowledged under FIFRA Section 3(c)(1)(D) only if the Agency has established that one product is substantially similar to another product for which the Agency has received acceptable data.

Table III.A-1 Generic Data Requirements for Magnesiun Phosphide, Product Chemistry (see Part IV)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.61-3	Product Identity:					
	- Identity of ingredients	yes	Technical grade of active ingredient	partial[1/]	GS0097005	yes/8 months
	- Statement of composition	yes		partial[1/]	GS0097005	yes/8 months
163.61-4	Manufacturing process, described	yes	Technical grade of active ingredient	partial[2/]	GS0097005	yes/8 months
163.61-5	Discussion on formation of impurities	yes	Technical grade of active ingredient	partial[2/]	GS0097005, GS0097002	yes/8 months
163.61-6	Composition limits:					
	- Actives, all	yes	Technical grade of active ingredient	no	-	yes/8 months
	- Impurities >0.1%	yes				
163.61-7	- Analytical methods	yes	Technical grade of active ingredient	partial[3/]	GS0097005	yes/8 months
	- Composition data	yes	Technical grade of active ingredient	partial[3/]	GS0097005	yes/8 months
163.61-8(c)(1)	Color	yes	Technical grade of active ingredient	partial[1/]	GS0097005	yes/8 months

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Table III.A-1 Generic Data Requirements for Magnesium Phosphide, Product Chemistry (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.61-8(c)(2)	Odor	yes	Technical grade of active ingrdient	partial[1]	GS0097005	yes/8 months
163.61-8(c)(3)	Melting Point	yes	Technical grade of active ingredient	partial[1]	GS0097005	yes/8 months
163.61-8(c)(4)	Solubility	yes	Technical grade of active ingredient	partial[4]	GS0097005	yes/8 months
163.61-8(c)(5)	Stability	yes	Technical grade of active ingredient	partial[1]	GS0097005	yes/8 months
163.61-8(c)(6)	Octanol/Water Partition Coefficient	no[5]				
163.61-8(c)(7)	Physical State	yes	Technical grade of active ingredient	yes	GS0097005	no
163.61-8(c)(8)	Density or Specific Gravity	yes	Technical grade of active ingredient	partial[1]	GS0097005	yes/8 months

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Table III.A-1 Generic Data Requirements for Magnesium Phosphide, Product Chemistry (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.61-8(c)(9)	Boiling Point	no[5/]				
163.61-8(c)(10)	Vapor Pressure	no[5/]				
163.61-8(c)(11)	pH	no[5/]				

1/ Even though some of the data requirements have been partially or completely fulfilled for some technical grade of active ingredients used to formulate end-use products, the Agency has not received data to support all end-use products. These data requirements must be met by each applicant at the time of registration or reregistration. Note: Currently, no technical grade of the active ingredient is registered.

2/ Patent literature reviewed for the Zinc Phosphide Standard (Tanaka, 1968, MRID #005014567) indicates impurities associated with zinc phosphide include both phosphorus and zinc diphosphide (ZnP_2); it would be reasonable to assume similar impurities, MgP_2 and phosphorus, occur in technical magnesium phosphide. Information and data more specifically related to the impurities in magnesium phosphide is required.

3/ The Agency has received acceptable methodology for the analysis of both the technical magnesium phosphide and registered products, whether for manufacturing-use or end-use. The Agency, however, has not received analytical results by this procedure for the registered compositions. Such results are also required for technical magnesium phosphide which is used to produce registered products.

4/ Data are required for the solubility of the technical material in commom solvents (e.g., chloroform, carbon disulfide) in accordance with the Guideline's standard of acceptable testing.

5/ These physical/chemical property data requirements are not needed to support the registration of products under this Standard for the following reasons: 1) property #6 (Octanol/Water Partition Coefficient) is not required for compounds like magnesium phosphide which are highly ionic or which are decomposed by water; 2) properties #9 (Boiling Point) and #10 (Vapor Pressure) are not required because the technical material is a solid at room temperature; and 3) property #11 (pH) is not required because the active ingredient is insoluble or is decomposed by water.

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Table III.A-2 Generic Data Requirements for Magnesium Phosphide, Environmental Fate (see Part V)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.62-7(b)	Hydrolysis[1]	yes	Phosphine[2]	no	-	yes/14 months
163.62-8(f)	Microbial metabolism (3) effects of pesticides on microbes	yes	3/	no	-	3/
163.62-8(g)	Activated sludge metabolism	yes	3/	no	-	3/
163.62-9(c)	Volatility[1]	yes	Phosphine[2]	no	-	yes/14 months
163.62-12	Reentry[1]	yes	Phosphine[2]	partial[4]	000005735, 000005691, 000005737, 000005662, 000005797, 000005664	yes/14 months
163.62-13	Disposal and Storage	no[5]				

Table III.A-2 Generic Data Requirements for Magnesium Phosphide, Environmental Fate (see Part V) (cont'd)

1/ While the available phosphine toxicology studies are inadequate, the Agency believes that in most cases the actual exposure to phosphine is sufficiently low that a worst case analysis will support present uses of magnesium phosphide in the absence of additional phosphine toxicology studies. However, the Agency requires additional exposure monitoring data to support the conclusion that current levels of phosphine exposure are toxicologically insignificant. Therefore, for each site or similar group of sites for which entry into treated (confined) areas is likely, the Agency requires adequate exposure monitoring data. Data should measure the actual concentration(s) of phosphine to which workers will be exposed following reentry into treated (confined) areas when following accepted magnesium phosphide label directions. To preclude unnecessary studies from being conducted, the registrant is strongly urged to consult with appropriate Agency scientists (i.e., Hazard Evaluation Division, Office of Pesticide Programs) before initiating the phosphine exposure monitoring studies. For useful background information, consult the reference to hydrolysis and volatility in the Agency's Guidelines. The Agency will accept the data generated under the Aluminum Phosphide Registration Standard (EPA, 1981) to support the registration/reregistration of products containing magnesium phosphide.

2/ Because magnesium phosphide reacts with water to release the fumigant, phosphine, studies should analyze phosphine concentrations.

3/ The requirement for submission of these data is currently being reserved pending the review and modification of testing protocols. Because the use patterns (enclosed areas) currently registered are not similar to other agricultural pesticides (outdoor), the Agency is re-examining the need for these data requirements.

4/ The kinetics of phosphine release and dissipation cannot be determined quantitatively from these studies.

5/ Data necessary to meet this requirement will be provided by data from Section 163.62-7(b), 163.62-8(f)(3), and 163.62-8(g).

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Table III.A-3 Generic Data Requirements for Magnesium Phosphide, Toxicology (see Part VI)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.81-1	Acute Oral Toxicity	yes	Technical grade of active ingredient	no	-	no[1]
163.81-2	Acute Dermal Toxicity	yes	Technical grade of active ingredient	no	-	no[1]
163.81-3	Acute Inhalation Toxicity	yes	Technical grade of active ingredient	partial[2]	005007354	no[1]
163.81-4	Primary Eye Irritation	yes	Technical grade of active ingredient	no	-	no[1]
163.81-5	Primary Dermal Irritation	yes	Technical grade of active ingredient	no	-	no[1]
163.81-6	Dermal Sensitization	no[3]				
163.81-7	Acute Delayed Neurotoxicity	no[4]				

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Table III.A-3 Generic Data Requirements for Magnesium Phosphide, Toxicology (see Part VI) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.82-1	Subchronic Oral	yes	Technical grade of active ingredient	no	-	reserved[5/]
163.82-2	Subchronic Dermal	no[3/]				
163.82-4	Subchronic Inhalation	yes	Technical grade of active ingredient	no	-	reserved[6/]
163.82-5	Subchronic Neurotoxicity	no[4/]				
163.83-1	Chronic Feeding Study	yes	Technical grade of active ingredient	no	-	reserved[5/]
163.83-2	Oncogenicity	yes	Technical grade of active ingredient	no	-	reserved[5/]
163.83-3	Teratogenicity	yes	Technical grade of active ingredient	no	-	reserved[6/]

Table III.A-3 Generic Data Requirements for Magnesium Phosphide, Toxicology (see Part VI) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.82-4	Reproduction	yes	Technical grade of active ingredient	no	-	reserved[5]
163.84-1 163.84-2 163.84-3 163.84-4	Mutagenicity	yes	Technical grade of active ingredient	no	-	reserved[6]
163.85-1	Metabolism	yes	Radiolabeled analytical grade	no	-	reserved[6]

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[1] The acute toxicity studies are required for labeling purposes. The severest labeling restriction (i.e, the signal word DANGER and skull and crossbones) has been imposed on the end-use magnesium phosphide products due to the highly acute inhalation toxicity of phosphine which can be readily evolved from the formulation. Therefore, all of the acute toxicity requirements on the technical grade of active ingredient products have been waived.

[2] This study was considered supplementary because only one sex was tested and complete details concerning all test parameters were not provided.

[3] This study is required when repeated dermal exposures are expected with the end-use products. No dermal exposure to these formulations is expected.

[4] Magnesium phosphide or phosphine are not organophosphorus compounds nor do they produce cholinesterase inhibition.

[5] These requirements are being reserved until the Agency receives and reviews the residue chemistry data (e.g., identification of unknown residues). If the Agency determines that these unidentified phosphine residues are toxicologically significant, these studies may be required.

[6] These requirements are being reserved until the Agency receives and reviews the required environmental fate data (e.g., volatility and reentry). If there is any exposure to phosphine during reentry, the Agency may require these studies.

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Table III.A-4 Generic-Data Requirements for Magnesium Phosphide, Residue Chemistry (see Part VII)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
-	Nature of the Residue	yes	-	partial[1]	005018681, 005008303, 005007621, 005008840, 005015384, 005013027, 005020467, 000005813, 005012115	yes/12 months
-	Metabolism in Animals	no[2]				
-	Analytical Methods	yes	-	yes	005007190, 005007724,[3] 005007845	no
-	Residue Data:					
	1. Raw Agricultural Commodities	yes	-	yes	005007190, 000006724, 005013439, 005016260, 005022032, 000005750, 005013276, 000005671, 005012293, 000005905, 000005767, 000005719, 005007845, 000005685, 000005935, 005007830, 005019407, 005014054, 000005686, 000005781, 000005783, 005020562, 005020467, 005016893, 000005696, 005015520, GS0097002	no

Table III.A-4 Generic-Data Requirements for Magnesium Phosphide, Residue Chemistry (see Part VII) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Compostion	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
-	Residue Data (cont'd):					
	2. Processed Foods and Feeds	yes	-	yes	000005750, 000005775, 000022007, 000022026, 000005776, 000005774, 000005786, 000022008, 000005696, 000022015, 000022017, 005012293, 000005777, 000005768, 000005905, 005007190, 000005935, 000020578, 005022032, 000022913, GS0097002	no
	3. Milk, Meat, Eggs and Poultry	no[2/]				
-	Residue Data Following Aeration of Commodity	yes	-	yes	000020578, 000022017, 000005686	no
-	Storage Stability Data for Residues in Commodities	no[2/]				

Table III.A-4 Generic-Data Requirements for Magnesium Phosphide, Residue Chemistry (see Part VII) (cont'd)

1/ In support of this Standard, recent studies (see Part VII) conducted with radiolabeled phosphine (^{32}P), were reviewed which indicate phosphine reacts irreversibly with grain and other fumigated commodities to form oxy-acids of phosphorous and unidentified, water-insoluble, residue(s). The Agency is therefore requesting further study on the nature of the residue, specifically that the unidentified residue (*ca* 0.7 ppm) be identified. After reviewing the requested data, if the Agency cannot determine that these unidentified residues are toxicologically insignificant, the Agency may request additional studies to support the continued registration of magnesium phosphide products (refer to those data requirements indicated by footnote #2). The Agency will accept the data generated under the Aluminum Phosphide Registration Standard (EPA, 1981) to support registration/reregistration of products containing magnesium phosphide.

2/ Because of the very small residues of phosphine which result from the currently accepted uses of magnesium phosphide, the fugitive nature of phosphine *per se*, and the labeling restriction against mixing the end-use products with animal feeds, the Agency will not require these data at this time. However, if the Agency determines that these unidentified residues are toxicologically significant, these studies may be required.

3/ An acceptable analytical method can also be found in Volume II of the Pesticide Analytical Manual (PAM), Pesticide Reg. Sec. 180.225, 1981 Edition (Note: PAM is published and revised periodically by the Food and Drug Administration).

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Table III.B-1 Product-Specific Data Requirements for Magnesium Phosphide Manufacturing-Use Products, Product Chemistry (see Part IV)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.61-3	Product Identity:					
	- Identity of ingredients	yes	Each manufacturing-use product	no	-	yes/8 months[1]
	- Statement of composition	yes		no	-	yes/8 months[1]
163.61-4	Manufacturing process, described	yes	Each manufacturing-use product	no	-	yes/8 months[1]
163.61-5	Discussion on formation of impurities	yes	Each manufacturing-use product	no	-	yes/8 months[1]
163.61-6	Certified limits:		Each manufacturing-use product			
	- Actives, all	yes		no	-	yes/8 months[1]
	- Impurities >0.1%	yes		no	-	yes/8 months[1]
163.61-7	- Analytical methods	yes	Each manufacturing-use product	partial[2]	GS0097005	yes/8 months[1]
	- Composition data	yes	Each manufacturing-use product	partial[2]	GS0097005	yes/8 months[1]

Table III.B-1 Product-Specific Data Requirements for Magnesium Phosphide Manufacturing-Use Products, Product Chemistry (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.61-8 Physical/Chemical Property Data[3]						
-8(c)(1)	Color	yes	Each manufacturing-use product	no	--	yes/8 months[1]
-8(c)(2)	Odor	yes	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(7)	Physical State	yes	Each manufacturing-use product	partial	GS0097005	yes/8 months[1]
-8(c)(8)	Density	yes	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(11)	pH	no[4]				
-8(c)(12)	Storage Stability	yes	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(13)	Flammability	yes[4]	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(14)	Oxidizing/Reduction	yes	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(15)	Explosiveness	yes	Each manufacturing-use product	no	--	yes/8 months[1]

Table III.B-1 Product-Specific Data Requirements for Magnesium Phosphide Manufacturing-Use Products, Product Chemistry (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.61-8 Physical/Chemical Property Data (cont'd)3/						
-8(c)(16)	Miscibility	no4/				
-8(c)(17)	Viscosity	no4/				
-8(c)(18)	Corrosion Characteristics	yes	Each manufacturing-use product	no	-	yes/8 months1/
-8(c)(19)	Dielectric Breakdown Voltage	no4/				

1/ Even though some of the requirements have been partially or completely fulfilled for some products, references cannot be cited to support other products, except for 163.61-7. These data are not required to be submitted since there are currently no manufacturing-use products registered; data indicated will be required to support the registration of each such product at the time of registration. Note: The data requirements for products intended for manufacturing-use and those end-use products produced by an intergrated-formulation system are the same.

2/ The Agency has received acceptable methodology for the analysis of both the technical magnesium phosphide and registered products, whether for manufacturing-use or end-use. Such results are required to establish the composition limits which the registrant certifies for his product.

3/ For the technical magnesium phosphide used to formulate the manufacturing-use product, a description of the manufacturing process and discussion on the formation of ingredients are required. Data are also required for the physical/chemical properties as indicated in Table III.A-1.

4/ These physical/chemical property data requirements are not needed to support the registration of products under this Standard for the following reasons: 1) property #11 (pH) is not required because the active ingredient is insoluble and decomposes in water; 2) property #13 (Flammability) is normally required only for flammable liquids. (However, because of the flammable nature of magnesium phosphide, flammability data in accordance with the guideline requirements will be needed for manufacturing-use products); 3) properties #16 (Miscibility) and #17 (Viscosity) are required only for liquids; and 4) property #19 (Dielectric Breakdown Voltage) is not required because the product is not applied directly to electrical wires.

ble III.B-2 Product-Specific Data Requirements for Manufacturing-Use Magnesium Phosphide Products, Toxicology (see Part VI)

idelines tation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
3.81-1	Acute Oral Toxicity	yes	Each manufacturing-use product	no	-	no[1]
3.81-2	Acute Dermal Toxicity	yes	Each manufacturing-use product	no	-	no[1]
3.81-3	Acute Inhalation Toxicity	yes	Each manufacturing-use product	partial[2]	005007354	no[1]
3.81-4	Primary Eye Irritation	yes	Each manufacturing-use product	no	-	no[1]
3.81-5	Primary Dermal Irritation	yes	Each manufacturing-use product	no	-	no[1]
3.81-6	Dermal Sensitization	no[3]				

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Table III.B-2 Product-Specific Data Requirements for Manufacturing-Use Magnesium Phosphide Products, Toxicology (see Part VI) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.81-7	Acute Delayed Neurotoxicity	no[4/]				

1/ The acute toxicity studies are required for labeling purposes. The severest labeling restriction (i.e., the signal word DANGER and skull and crossbones) has been imposed on the end-use magnesium phosphide products due to the highly acute inhalation toxicity of phosphine which can be readily evolved from the formulation. Therefore, all of the acute toxicity requirements on the manufacturing-use products have been waived.

2/ This study was considered supplementary because only one sex was tested and complete details concerning all test parameters were not provided.

3/ This study is required when repeated dermal exposures are expected. No dermal exposure to these formulations is expected.

4/ Magnesium phosphide or phosphine are not organophosphorus compounds nor do they produce cholinesterase inhibition.

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Table III.C-1 Product-Specific Data Requirements for Magnesium Phosphide End-Use Products, Product Chemistry[1] (see Part IV)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.61-3	Product Identity:					
	- Identity of ingredients	yes	Each end-use product	yes	GS0097005, GS0097006, GS0097007, GS0097008, GS0097009	no
	- Statement of composition	yes	Each end-use product	yes	GS0097005, GS0097006, GS0097007, GS0097008, GS0097009	no
163.61-4	Manufacturing process, described	yes	Each end-use product	partial[2]	GS0097005	yes/8 months
163.61-5	Discussion on formation of impurities	yes	Each end-use product	partial[2]	GS0097005	yes/8 months
163.61-6	Certified limits:		Each end-use product			
	- Actives, all	yes		no	-	yes/8 months
	- Impurities > 0.1%	yes		no	-	yes/8 months
163.61-7	- Analytical methods	yes	Each end-use product	partial[3]	GS0097005	yes/8 months
	- Composition data	yes	Each end-use product	partial[3]	GS0097005	yes/8 months

Table III.C-1 Product-Specific Data Requirements for Magnesium Phosphide End-Use Products, Product Chemistry[1] (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.61-8	Physical/Chemical Property Data					
-8(c)(1)	Color	yes	Each end-use product	no	-	yes/8 months
-8(c)(2)	Odor	yes	Each end-use product	no	-	yes/8 months
-8(c)(7)	Physical State	yes	Each end-use product	yes[4]	-	yes/8 months
-8(c)(8)	Density or Bulk Density	yes	Each end-use product	no	-	yes/8 months
-8(c)(11)	pH	no[5]				
-8(c)(12)	Storage Stability	yes	Each end-use product	no	-	yes/8 months
-8(c)(13)	Flammability	yes[5]	Each end-use product	no	-	yes/8 months
-8(c)(14)	Oxidizing/Reduction	yes	Each end-use product	no	-	yes/8 months
-8(c)(15)	Explosiveness	yes	Each end-use product	no	-	yes/8 months
-8(c)(16)	Miscibility	no[5]				
-8(c)(17)	Viscosity	no[5]				

Table III.C-1 Product-Specific Data Requirements for Magnesium Phosphide End-Use Products, Product Chemistry1/ (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.61-8 Physical/Chemical Property Data (cont'd)						
-8(c)(18)	Corrosion Characteristics	yes	Each end-use product	no	-	yes/8 months
-8(c)(19)	Dielectric Breakdown Voltage	no 5/				

1/ Even though some of the requirements have been partially or completely fulfilled for some products, references cannot be cited to support other products, except for 163.61-7. These requirements must be submitted by each applicant at the time of registration or reregistration. Data indicated in Table III.A-1 will also be required to support the registration of each end-use product since no technical grade or manufacturing-use products are registered. The data requirements for products intended for manufacturing-use and those end-use products produced by an intergrated-formulation system are the same.

2/ Patent literature reviewed for the Zinc Phosphide Standard (Tanaka, 1968, MRID #005014567) indicates impurities associated with zinc phosphide include both phoshporus and zinc diphosphide (ZnP_2); it would be reasonable to assume similiar impurities, MgP_2 and phosphorus, occur in technical magnesium phosphide. Information and data more specifically related to the impurities in magnesium phosphide are required.

3/ The Agency has received acceptable methodology for analysis of both the technical magnesium phosphide and registered products, whether for manufacturing-use or end-use. The Agency, however, has not received analytical results by this procedure for the registered compositions. Such results are required to establish the composition limits which the registrant certifies for his product.

4/ The Agency has information to support all currently registered end-use products [information was provided in the Confidential Statement of Formula (CSF)].

5/ These physical/chemical property data requirements are not needed to support the registration of products under this Standard for the followin reasons: 1) property #11 (pH) is not required because the active ingredient is insoluble and decomposes in water; 2) property #13 (Flammability) is normally required only for flammable liquids. (However, because of the flammable nature of magnesium phosphide, flammability data in accordance with the guideline requirements will be needed.); 3) properties #16 (Miscibility) and #17 (Viscosity) are required only for liqu and 4) property #19 (Dielectric Breakdown Voltage) is not required because the product is not applied directly to electrical wires.

Table III.C-2 Product-Specific Data Requirements for End-Use Magnesium Phosphide Products, Toxicology (see Part VI)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.81-1	Acute Oral Toxicity	yes	Each end-use product	no	-	no[1]
163.81-2	Acute Dermal Toxicity	yes	Each end-use product	no	-	no[1]
163.81-3	Acute Inhalation Toxicity	yes	Each end-use product	partial[2]	005007354	no[1]
163.81-4	Primary Eye Irritation	yes	Each end-use product	no	-	no[1]
163.81-5	Primary Dermal Irritation	yes	Each end-use product	no	-	no[1]
163.81-6	Dermal Sensitization	no[3]				

Table III.C-2 Product-Specific Data Requirements for End-Use Magnesium Phosphide Products, Toxicology (see Part VI) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when due.
163.81-7	Acute Delayed Neurotoxicity	no[4/]				

1/ The acute toxicity studies for end-use products are required for labeling purposes. The severest labeling restriction (i.e., the signa word DANGER and skull and crossbones) has been imposed on the end-use magnesium phosphide products due to the highly acute inhalation toxicity of phosphine which can be readily evolved from the formulation. Therefore, all of the acute toxicity requirements on the end-use products have been waived.

2/ This study was considered supplementary because only one sex was tested and complete details concerning all test parameters were not provided.

3/ This study is required when repeated dermal exposures are expected. No dermal exposure to these formulations is expected.

4/ Magnesium phosphide or phosphine are not organophosphorus compounds nor do they produce cholinesterase inhibition.

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IV. Product Chemistry

A. Introduction

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. Subpart D of these guidelines requires a registrant to provide data on the composition of his product and the physical and chemical properties of both the formulated product and the active ingredient(s) in the product. These data are needed by the Agency to characterize products and to assess environmental and health effects from their use.

To evaluate product composition, the Agency requires: 1) the submission of a detailed manufacturing process for pesticides including data on the composition of starting and intermediate materials; 2) a discussion of the presence in a product of unintentional ingredients formed during, or subsequent to, manufacture; 3) declaration of the upper and lower limits for each active and intentionally added inert ingredient, and the upper limit for each impurity; 4) certification that ingredient limits will be maintained for all quantities of the product sold or distributed in commerce; and 5) analytical methods, and data obtained by these methods, for each active ingredient and identifiable impurity at or in excess of 0.1% of the product weight. The Agency may require methods and data for impurities below 0.1% of the product weight when highly toxic impurities are present.

The Agency also requires data on the physical and chemical properties of the pesticide. For example, data are needed concerning the identity and physical state of the active ingredient (e.g., melting and boiling points, vapor pressure, and solubility). Data are also required on those properties of the formulated product that are clearly related to necessary labeling cautions (e.g., flammability, corrosion characteristics, and storage stability).

To assist applicants in meeting these requirements and to accelerate the Agency's review and evaluation of the submitted data, the guidelines include criteria for acceptable testing of products and an appendix with references to literature sources containing appropriate testing protocols.

B. Chemical Identity

In the United States, magnesium phosphide is the preferred name for the pesticide which is the subject of this Registration Standard. It is also the name recommended by the American Chemical Society's Chemical Abstracts Service (CAS). Additional identifying characteristics of magnesium phosphide include: molecular formula, Mg_3P_2; CAS Registry No., 12057-74-8; and molecular weight, 134.87.

Information and data contained in Pesticide Petition 7F1985 (Phostoxin Sales, Inc., 1977, MRID #GS0097003) show that magnesium phosphide is stable when dry, but reacts with water, including atmospheric moisture, to liberate the fumigant phosphine. The petition also includes the molecular formula for phosphine, PH_3; its molecular weight, 34.00; and its CAS Registry No., 7803-51-2.

C. Manufacturing Process

All of the end-use products of magnesium phosphide which the Agency has registered are produced by the integrated-formulation system technique (i.e., formulated with a technical magnesium phosphide, the composition of which is not registered with the Agency). To support such registrations, the guidelines require from each registrant a description of the manufacturing process for the technical magnesium phosphide used to formulate the product from each registrant.

To be considered adequate, a description must indicate whether the technical magnesium phosphide is produced by a continuous or batch process, provide information and data on the "beginning" or starting materials (e.g., their identity and composition), the manufacturing equipment, the physical conditions controlled during the process, and a flowchart listing the chemical reactions (and their duration) which are used to manufacture the technical magnesium phosphide. This description must also indicate any impurities that may be present in the technical material and any purification steps included in the manufacturing process.

On the basis of the above criteria, the information and data received by the Agency on the manufacturing process of magnesium phosphide are not adequate. For information and data which the Agency has received on the manufacturing/formulating process for magnesium phosphide, see the Confidential Annex, Part IX; product composition data are protected under Section 10 of FIFRA.

D. Discussion on the Formulation of Impurities (and Unintentional Ingredients)

In accordance with the product chemistry guidelines (Section 163.61-5), the registration of each magnesium phosphide product produced by an integrated-formulation system must be supported by a discussion of the impurities that may be present in the product at a level equal to or greater than 0.1% (1,000 ppm). The discussion is to be based on established chemical theory and the required description of the manufacturing process (Section 163.61-4), with consideration given to the impurities present in both the manufacturing reactants and formulating materials. Data to meet this requirement have not been submitted to support the registration of any magnesium phosphide product.

E. Declaration and Certification of Ingredient Limits

The Confidential Statements of Formula for the products registered under this Standard (those containing magnesium phosphide as the sole source for generating the active agent, phosphine) should be revised to indicate upper and lower limits for both the magnesium phosphide and any intentionally added inerts which are $\geq$0.1%. Upper limits must be stated for all impurities >0.1% and any other impurities (<0.1%) which might increase the potential hazards of the product (i.e., impurities that might increase the amount of diphosphine which is evolved with phosphine). Such impurities would include binary compounds of magnesium and phosphorus other than magnesium phosphide (Mg_3P_2).

BEST DOCUMENT AVAILABLE

F. Product Analytical Methods and Data

Official methods of analysis by the Association of Official Analytical Chemists (AOAC), or by similar organizations, have not been established for magnesium phosphide. However, the submissions reviewed for the Aluminum Phosphide Registration Standard indicated a procedure which would also be applicable to the formulations of magnesium phosphide. In this procedure, the metallic (aluminum, magnesium or zinc) phosphide content of the product is calculated on the basis of evolved phosphine. The analysis is accomplished by reacting the product with water and acid; the phosphide is converted to phosphine; the phosphine is swept with nitrogen into an adsorption vessel containing a solution of mercuric (II) chloride; a reaction occurs [$PH_3 + 3HgCl_2 \rightarrow P(HgCl)_3 + 3HCl$]; the hydrochloric acid produced is titrated with standard alkali; and the metal phosphide content is then calculated. The basis of this procedure was suggested in 1953 by White and Bushey (MRID #005010196) [Also see EPA Manual of Chemical Methods for Pesticides and Devices].

If the technical magnesium phosphide contains a manufacturing impurity for which an upper limit must be certified because it may increase the potential hazard of end-use products, the manufacturer will be required to provide suitable methodology for monitoring this impurity in registered products.

G. Physical and Chemical Property Data

Because magnesium phosphide has not been registered as a manufacturing-use product, the product chemistry data requirements (as specified by the guidelines) are those of an end-use product produced by an integrated-formulation system. For such end-use products, data are normally required for the properties numbered 1, 2, 7, 8 and 11 through 19 in Table VI.A. For the unregistered technical grade of magnesium phosphide used to formulate such end-use products, data are normally required for properties #1 through #11. However, because of the special characteristics of magnesium phosphide, some of these requirements would not be applicable to either the technical grade or to the registered products, whether for end-use or manufacturing-use. These exceptions and the requirements for data on the physical/chemical properties of both the unregistered technical magnesium phosphide and registered products are summarized in Table IV.A.

TABLE IV.A

Physical/Chemical Properities for Magnesium Phosphide

Physical/Chemical Property	End-use products (MRID #)	Technical material (MRID #)
(1) Color	Data Required	Data required
(2) Odor	Data required	Data required
(3) Melting point	Not required	Data required
(4) Solubility	Not required	Data required 1/
(5) Stability	Not required	Data required 2/
(6) Octanol/Water partition coefficient	Not required	For ionic compounds; not required
(7) Physical state	Solids, all products	Crystalline (GS0097005)
(8) Density (or bulk density)	Data required	Data required
(9) Boiling point	Not required	Not required, need for liquids only
(10) Vapor pressure	Not required	Not required, products are solid at room temperature
(11) pH	Not required	Not required (decomposes in water)
(12) Storage stability	Data required	Not required
(13) Flammability	Data required 3/	Not required
(14) Oxidizing/Reduction Potential	Data required 3/	Not required

TABLE IV.A (Cont'd)

Physical/Chemical Properities for Magnesium Phosphide

Physical/Chemical Property	End-use products (MRID #)	Technical material (MRID #)
(15) Explosiveness	Data required 3/	Not required
(16) Miscibility	Not required; need for liquids only	Not required
(17) Viscosity	Not required; need for liquids only	Not required
(18) Corrosion Characteristics	Data required	Not required
(19) Dielectric Constant Voltage	Not required; because the applicator does not directly applied Mg_3P_2 to electrical components	Not required

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1/ For each technical composition of magnesium phosphide, data are needed for its solubility in common laboratory solvents (e.g., chloroform and carbon disulfide) in accordance with the Guideline's standards for acceptable testing.

2/ Data showing the effect of small amounts of impurities (alkali, acids, and metallic ions) on the stability of technical magnesium phosphide are needed.

3/ Flammability, oxidizing/reductions, and explosiveness data are required for magnesium phosphide products in accordance with the guideline requirements for acceptability. Such data are required because of the chemical similarity of phosphides of magnesium, aluminum and zinc, and because the U.S. Dept. of Transportation classified the phosphides of both zinc and aluminum as flammable solids. It should be noted that flammability and explosion hazards of these products are also associated with the evolution of phosphine. Phosphine, like other ignitable gases, is explosive in air between certain concentrations. For phosphine these concentrations are, by volume, 1.79% to 1.89% or about 26 mg/liter (Dittmar, 1960, MRID #000005669).

Additional information on the explosiveness of phosphine was also provided. According to a submission (Duford, 1961, MRID #000005681) reviewed for the Aluminum Phosphide Registration Standard, the heat (which might be provided by a heated surface) and the temperature (between 100-150°C) needed to initiate ignition of phosphine is partly dependent upon the presence of evolved impurities, such as diphosphine (P_2H_4) and higher phosphines. For aluminum phosphide and presumably for magnesium phosphide, the purity of the evolved phosphine is dependent upon the purity of the phosphide (Fluck, 1973, MRID #000005813). The submission by Duford (1961, MRID #000005681) also included data for the ignition of phosphine-air concentrations typical of those used to fumigate wheat and other commodities, whether from products of aluminum phosphide or magnesium phosphide.

H. Summary of Data Gaps

Data reviewed during the development of the Aluminum Phosphide Registration Standard (EPA, 1981) indicate that the flammability and explosive hazards associated with phosphine fumigation were increased by the presence of small amounts of diphosphine (P_2H_4) and other impurities which were evolved with the phosphine. Because the amount of such evolved impurities increased when the aluminum phosphide was not pure, the Agency required for aluminum phosphide information and data on the manufacturing process together with the discussion on product impurities specified by Sections 163.61-4 and -5 of the guidelines. These data are also required for magnesium phosphide. The product chemistry data gaps for magnesium phosphide products are detailed in Tables III.A-1, B-1 and C-1 of Part III.

V. Environmental Fate

A. Use Summary

Magnesium phosphide is a fumigant registered for the control of insects, primarily Coleoptera and Lepidoptera, in raw agricultural commodities, processed food, animal feed, and nonfood/nonfeed products (including tobacco) stored in warehouses, grain elevators, and ships. Phosphine gas, generated from the reaction of magnesium phosphide with ambient moisture, is the toxic agent. No data were found for annual sales volume of this pesticide, possibly because it has not yet been marketed. In addition to the previously mentioned uses, magnesium phosphide is registered for use as a rodenticide.

Magnesium phosphide is available as 32.3% active ingredient plates and 66% active ingredient pellets and tablets for space fumigation, and as 49.6% active ingredient discs for rodent control. As a restricted use pesticide, magnesium phosphide can be applied only by certified applicators. Pellets and plates are placed in moisture permeable envelopes and located in storage areas without contact with the food/feed commodity. Spent material is disposed of by burial or by saturating with water. Treated areas must be placarded with warning signs until completely aerated and safe for reentry.

The Agency has given acceptance for magnesium phosphide as a restricted use rodenticide for the control of burrowing moles and rodents: Marmot sp. [woodchucks and yellow-belly marmot (rockchucks)], prairie dogs (except Utah prairie dogs), Norway and roof rats, ground squirrels, voles, house mice, gophers, and chipmunks. The products can only be used in noncrop areas and must not be applied within 15 feet of inhabited structures (i.e., the distance of linear diffusion for phosphine gas does not exceed 15 feet under this application condition) or to burrows which may open under or into occupied buildings. Magnesium phosphide is applied by adding 1 to 2 discs (formulated product) to the rodent burrow, packing the opening with crumpled newspaper and finally sealing the opening tightly by shoveling soil over the entrance. The newspaper prevents the soil from covering the discs and slowing their action. The lower rate (1 disc) is required for smaller burrows (e.g., rats, voles, ground squirrels, house mice, chipmunks) or under moist soil conditions, and the higher rate (2 discs) for larger burrows (e.g., woodchucks, prairie dogs, gophers) or when the soil moisture is very low. Reopened burrows may be retreated 1 to 2 days after initial treatment. Because of the small amount of product used in this manner, the Agency does not expect the phosphine gas liberated from the magnesium phosphide product to remain in soil or water, or to remain in the vapor state for an extended period of time. Thus, an assessment of potential reentry hazard is not necessary for this use.

B. Environmental Fate Profile

No data were found as to the fate of magnesium phosphide. Because of similar use patterns, the Agency believes that the following information about aluminum phosphide would apply to magnesium phosphide.

1. Microbiological - Effects of Pesticides on Microbes.

Ruschel and DaCosta (1966, MRID #005016261) treated "Rico 23" bean (Phaseolus vulgaris L.) seeds with aluminum phosphide by using three grams Phostoxin® tablets per cubic meter of defined area. Treated and control seeds were inoculated with a pure culture of Rhizobium phaseoli F33 (a nitrogen-fixing bacterium), sown in pots containing sandy soil (pH 4.5), and maintained under greenhouse conditions. The plants were sampled during the blooming period, and the following determinations for each plant were made: nodule number, dry weight, and percentage of nitrogen in the aboveground part of the plant. Phosphine had no apparent effect on nodulation (number of nodules) in bean plants grown from treated seed. However, the competency (i.e., ability to fix nitrogen) of the nodules was not reported.

2. Reentry

Childs et al. (1968?, MRID #000005691; 19??, MRID #000005735) reported phosphine gas concentrations in tobacco warehouses declined from 100-400 ppm to 1-5 ppm after aeration for 24 hours when fumigated with 3 grams aluminum phosphide tablets (55% AlP) at 20 tablets/1,000 cubic feet. Phosphine gas concentrations were the same at the 1- and 14-foot sampling heights above the floor. Concentrations of phosphine gas in air within tobacco hogsheads declined from 100-400 ppm to $\leq$13 ppm after aeration for 48 hours. Warehouse temperature and relative humidity were monitored continuously at a central point in the building with a 7-day hygrothermograph located 4 feet above the floor next to the center aisle. In all warehouses the temperature ranged from 68° to 96°F (20° to 35°C) and the relative humidity from 47 to 63%. However, temperature and humidity effects on phosphine gas release and dissipation were not discernible from the data.

Levels of phosphine gas peaked at 1,200 ppm 3 days after application of aluminum phosphide (Phostoxin® at 165 pellets/1,000 cubic feet, purity unspecified) in a polyethylene-covered enclosure containing lined fiberboard cases of tobacco (Edmond et al., 1971, MRID #000005737). Phosphine gas dissipated to nondetectable levels (<0.1 ppm) in air surrounding the cases 24 hours after removal of the cover even though the gas was present at 111-125 ppm inside the lined cases. Therefore, under warehouse conditions with aeration, the phosphine gas released from closed cases should be present at <0.1 ppm in the surrounding air.

Nelson (1970, MRID #000005797) found that phosphine concentrations in the air inside enclosed stacks of raisins peaked at 761 ppm and declined to 479 and 7 ppm within 6 and 50 days, respectively, after application of aluminum phosphide (purity unspecified) at 45 tablets/1,000 cubic feet. The rate of decline was not linearly related to the application rate. However, 99% of the phosphine gas inside enclosed stacks of raisins would be dissipated in the treated area 50 days after treatment without aeration. The level of phosphine gas in the treatment area with aeration was not determined for reentry.

Tuft (1960, MRID #000005664) detected phosphine gas in the air surrounding wheat* (approximately 200 pounds) treated with aluminum phosphide (Phostoxin®, 55% AlP) at 10 tablets per ton of wheat. The concentration in the air space around the wheat was 198 ppm one hour after treatment. This concentration had increased to a maximum level of 1,535 ppm at 56 hours after treatment and then decreased rapidly for about 150 hours without aeration. After 260 hours no phosphine was detected in the air surrounding the wheat. The level of phosphine gas in the treatment area with aeration was not determined for reentry.

Lauhoff Grain Company (1966, MRID #000005662) fumigated cornmeal in sealed boxcars with aluminum phosphide (Phostoxin®, 55% AlP) at a rate of 165 pellets/1,000 cubic feet. When whole pellets were used, phosphine gas levels 42-46 hours after fumigation ranged from <10 to 68 ppm (median 17)**. Data were extremely variable in boxcars treated with crushed or ground pellets, where phosphine gas concentrations ranged from <10 to 384 ppm (median 26) 24 hours after fumigation. Therefore, the kinetics of phosphine release and dissipation cannot be generalized from these data.

In summary, phosphine gas generated from aluminum phosphide pellets and tablets is expected to decline rapidly in treated areas upon aeration. These levels of phosphine gas in the air surrounding the treated commodities should not be confused with the amount of residues in or on treated commodities (see Part VII, Residue Chemistry). Temperature and moisture also influence the release and dissipation of phosphine gas, however, data from these studies were insufficient to assess these factors. Therefore, reentry intervals and the kinetics of phosphine release and dissipation cannot be determined quantitatively from these studies.

C. Exposure Profile

Adequate data are not available to fully assess the potential for exposure of humans and wildlife to magnesium phosphide. Soil mobility data for assessing the groundwater contamination potential and bioaccumulation data are not available; however, the registered uses of magnesium phosphide are not expected to result in these types of exposure hazards. Exposure of wildlife (nontarget organisms) is unlikely to occur for the insecticide uses, given the use of magnesium phosphide as a fumigant for enclosed areas. However, the Agency is concerned about the fumigation of rodent burrows which may result in exposure hazards to endangered species (see Part VIII, Ecological Effects).

The greatest potential for direct exposure of humans is during handling, application, and reentry operations. Respiratory exposure is expected to be the main route of exposure because the toxic agent, phosphine, is a gas. Data for quantifying such exposures are lacking. Preliminary studies show that concentrations of phosphine gas released during fumigation with aluminum phosphide decline rapidly in treated areas upon aeration (Childs et al., 19??, MRID# 000005735; Childs et al., 1968?, MRID #000005691; Edmond et al., 1971, MRID #000005737; Nelson, 1970, MRID #000005797; Tuft, 1960, MRID #000005664; and Lauhoff Grain Company, 1966, MRID #000005662). However, inconsistencies in the data make it impossible to quantitate the duration, air volume, and method of aeration required to dissipate phosphine gas to safe levels in the application sites. After the Agency receives and evaluates the Required reentry data for the insecticide use, the Agency may require that phosphide levels be monitored prior to reentering work areas*. Respirators jointly approved by the Mining Enforcement and Safety Administration (MESA) and the National Institute of Occupational Safety and Health (NIOSH) [designed for phosphine gas protection] should be worn by workers entering the fumigated areas until the phosphine gas dissipates to a safe level. The post-fumigation levels theoretically should decrease to some concentration approaching zero as the site is further aerated, but data are needed to determine the exposure levels, if any, to the applicator.

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* Air samples were removed at intervals (time) from a 60-gallon fiber drum containing common California red wheat through a glass tube inserted into the center of the drum, and approximately 2 feet below the surface of the grain.

** Samples of the gas were removed just before the boxcars were opened.

Dermal exposure may occur even when protective clothing is used because phosphine gas can penetrate a variety of materials, including polyethylene. Data for assessing such exposures are unavailable.

D. Summary of Data Gaps

The data gaps that are to be filled are hydrolysis, volatility and reentry**. There are data gaps relating to disposal and storage, microbial metabolism (effects of pesticides on microbes) and activated sludge metabolism. However, pending review and modification of the testing protocols or a reassessment for the necessity for these data (i.e., disposal and storage, microbial metabolism, and activated sludge metabolism), it is currently not necessary to satisfy these data gaps.

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* Due to the lower volume of use (one or two discs/burrow) and the use of the product away from inhabited areas, reentry data requirements will not be required for the rodenticide use.

** The Agency will accept the data generated under the Aluminum Phosphide Registration Standard (EPA, 1981) to support registration/reregistration of products containing magnesium phosphide.

VI. Toxicology

A. Introduction

Because of the highly toxic nature of phosphine and the ease with which it can be released from magnesium phosphide, the toxicity of magnesium phosphide has been assumed to be that of phosphine itself. Thus, the Agency has used the toxicological data on phosphine in regulating magnesium phosphide formulations and has not required the usual toxicological studies on magnesium phosphide or its formulations.

B. Application

The following discussion includes the application procedure which is required by the current labeling. The applicator, who must be certified, is required to notify the authorities such as the health departments, police departments and the fire departments so that any additional precautions may be taken, and emergencies may be handled promptly. The applicator should verify that the application site will properly contain the liberated phosphine and that the site is adequately secured against possible exposures to the surrounding areas. Posting warning signs and securing the areas with locks may be necessary to prevent workers from accidently entering a fumigated site.

After the magnesium phosphide is applied, concentrations of phosphine are allowed to build to the level (1,000 ppm may be necessary) needed for the fumigation process. Field sampling methods may be used to verify the level achieved within the site (above 1,000 ppm). "High level" air sampling tubes which measure phosphine levels from 15 to 3,000 ppm are commercially available. When checking the levels of phosphine, the applicators are required to wear gas masks and canisters jointly approved by the Mining Enforcement and Safety Administration (MESA) and the National Institute of Occupational Safety and Health (NIOSH). Such gas masks are to be retained at the fumigation site in cases of emergencies requiring entry into the site.

The applicator or his designee are required to measure the areas surrounding an application site to verify that there is no leakage from the site into surrounding living or working areas. For this, the applicator may use "low level" sampling tubes which measure levels of phosphine in the range of 0.1 to 4 ppm.

After the fumigation process is completed, the applicator is required to aerate the site until phosphine levels are at or below 0.3 ppm so that the site may be opened and workers may safely enter the area. The applicator should verify that the aeration procedures do not discharge directly into areas in which humans may be working or living. The applicator, wearing protective clothing and a respirator, measures the air over and around the commodity which has been fumigated using low-level sampling tubes to insure that phosphine levels are at or below 0.3 ppm.

For the rodenticide use, the magnesium phosphide is applied by placing 1 to 2 discs per burrow. The burrows are sealed tightly with soil over the entrance.

C. Toxicological Assessment

1. Acute Exposure Toxicity Summary

Table VI.A, Acute Inhalation Toxicity Summary for Phosphine, provides a comparison of different inhalation studies by descending chamber concentrations. Exposures generally lasted until animals started dying. Overall, the higher the concentration, the smaller the time interval to death. One study (Waritz and Brown, 1975, MRID #005007354) determined a LC_{50} concentration of 11 ppm or approximately 0.014 mg/liter. Although the study was classified as supplementary*, the LD_{50} derived from this study and information from the other studies cited in Table VI.A are sufficient to indicate that phosphine is highly toxic by the inhalation route, and for labeling purposes is in toxicity category I. Signs of toxicity resulting from acute exposure were primarily respiratory irritation and dyspnea (Waritz and Brown, 1975, MRID #005007354). The Agency requires no further acute toxicity studies using any route of administration (i.e., oral, dermal, inhalation, eye) for magnesium phosphide or phosphine.

2. Repeat Exposure Toxicity Summary

Table VI.B, Subchronic Inhalation Toxicity for Phosphine, summarizes the results of two major subchronic inhalation studies (Muller, 1940, MRID #GS0025022 and Klimmer, 1969, MRID #GS0025018). The results showed that as the exposure concentrations of phosphine decreased from 20 ppm to 5 ppm, the time interval to death generally increased. However, the increased time interval to death differed between the two studies.

Klimmer was able to maintain three species of animals without overt signs of toxicity for over 800 hours. The study was conducted over a six month period in which the test animals were exposure to phosphine at 2.5 ppm and 1 ppm for six hours/day for five days/week and four hours on Saturdays. At the next highest dose of 5 ppm, there were deaths in two of three species after approximately 30 hours. Thus, 2.5 ppm of phosphine can be considered as a no-observed-effect level (NOEL) for lethal effects and overt signs of toxicity during subchronic inhalation exposure.

Neither study would be judged adequate in evaluating all biological parameters deemed necessary by more modern toxicological requirements. Body weight changes, hematology, blood chemistry, organ weights, gross and histopathology evaluations were not performed in either study. Numbers of animals per dose were usually too low. Nevertheless, the studies do provide a good estimate of the dose-response relationship for the toxic effects of phosphine with different species.

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* This study is considered supplementary because only one sex was tested and complete details concerning all test parameters were not provided.

TABLE VI.A

Acute Inhalation Toxicity Study Summary for Phosphine

Concentration (ppm)	Exposure	Species	Time to Death	Citations
60,000-70,000	Continuous	Frog	3 hours	Brilliant, 1882[a]
2,500	25 minutes	Cat	51 minutes	Brilliant, 1882[a]
2,000	Continuous	Rabbit	33 minutes	Henderson & Bubois, 1879[a]
1,500	10 minutes	Rabbit	10 minutes	Meissner, 1924[a]
600	Continuous	Rat	1 hour	Rebmann, 1933[a]
540	Continuous	Mouse	35 minutes	Jakote, 1904[a]
403	46 minutes	Rat	36 minutes	Klimmer, 1969
400	30 minutes	Rabbit	50 minutes	Jakote, 1909[a]
300	Continuous	Guinea pig	2 hours	Rebmann, 1933[a]
205	75 minutes	Rat	66 minutes	Klimmer, 1969
167	100 minutes	Cat	93 minutes	Klimmer, 1969
167	100 minutes	Rabbit	90-98 minutes	Klimmer, 1969
167	100 minutes	Rat	70-75 minutes	Klimmer, 1969
160	Continuous	Hen	50-64 minutes	Klimmer, 1969
151	Continuous	Turkey	68, 74, 80 minutes	Klimmer, 1969
150	Continuous	Cat	160 minutes	Jakote, 1904[a]
140	110 minutes	Rat	97 minutes	Klimmer, 1969
120	130 minutes	Cat	103-130 minutes	Klimmer, 1969
120	130 minutes	Rabbit	110-125 minutes	Klimmer, 1969
120	130 minutes	Rat	79-123 minutes	Klimmer, 1969
60	Continuous	Rat	4 hours	Rebmann, 1933[a]
54	6.5 hours	Cat	5-6.5 hours	Klimmer, 1969
54	6.5 hours	Guinea pig	4-5.5 hours	Klimmer, 1969
54	6.5 hours	Rat	4-5.5 hours	Klimmer, 1969
50	150 minutes	Cat	4-5 hours	Jakote, 1904[a]
42-50	Continuous	Rat	5-7 hours	Muthu, 1980
25	4 hours	Guinea pig	4 hours	Muller, 1940
25	4 hours	Rabbit	4 hours	Muller, 1940
25	8.5 hours	Cat	8.5 hours	Klimmer, 1969
25	8.5 hours	Rabbit	5-8.5 hours	Klimmer, 1969
25	8.5 hours	Rat	7-8 hours	Klimmer, 1969
11 (0.014 mg/l)	4 hours	Rat	LC_{50}	Waritz & Brown, 1975

[a] Parkin, 1972.

Table VI.B

Subchronic Inhalation Toxicity Summary for Phosphine

Concentration (ppm)	Exposure [hr/day (hr) x days (d)]	Species	Time to death [hours (hr)or days (d)]	Reference
20	4 hr x 2 d	Rabbit	2 d	Muller, 1940
20	4 hr x 2 d	Guinea pig	2 d	Muller, 1940
14.8 and	4 hr x 6 d	Rabbit	6 d	Muller, 1940
10	4 hr x 7-14 d	Rabbit	7-15 d	Muller, 1940
8.3	4 hr x 4-5 d	Rabbit	4, 6 d	Muller, 1940
8.3	4 hr x 47 d	Rabbit	-	Muller, 1940
5	4 hr x 6 d	Rabbit	6 d	Muller, 1940
5	48 hr	Cat	35.5-45.5 hr	Klimmer, 1969
	(continuous)	Guinea pig	24-32 hr	Klimmer, 1969
		Rat	27-36 hr	Klimmer, 1969
5	80 hr	Guinea pig	30 hr	Klimmer, 1969
	(continuous)	Rat	32-48 hr	Klimmer, 1969
		Cat (2)	-	Klimmer, 1969
		Rat (2)	-	Klimmer, 1969
2.5	820 hr[a]	Cat	0/4[b]	Klimmer, 1969
		Guinea pig	0/4[b]	Klimmer, 1969
		Rat	0/10[b]	Klimmer, 1969
1	816 hr[a]	Cat	0/4[b]	Klimmer, 1969
		Rat	0/10[b]	Klimmer, 1969

a. Six hr/day, 5 day/wk, 4 hr on Saturdays.

b. Zero deaths out of four (or ten) treated animals.

Until the results of reentry data are received and evaluated concerning exposure to phosphine from registered uses of magnesium phosphide, the Agency will not request additional subchronic inhalation studies at this time*.

D. Human Poisoning Case Reports

The Agency does not have any information involving human pesticide exposure from magnesium phosphide possibly because magnesium phosphide has not been marketed since it was first registered in 1979 for use in the United States. However, the Agency does have information involving exposure to aluminum phosphide which releases the same toxic agent, phosphine, as magnesium phosphide.

The Agency's Pesticide Incident Monitoring System (1981) reported 29 incidents involving human pesticide exposure from aluminum phosphide. These incidents occurred from 1966 to March, 1981 and involved an estimated 80 to 90 people. Seventy-one of the exposed persons received medical treatment while an additional 33 persons were hospitalized, with a total of 2 fatalities.

In 22 incidents, pesticide exposure occurred when aluminum phosphide was used as a grain fumigant. Truck drivers, pesticide applicators, railroad, warehouse and mill workers, laborers and cargo crew members constituted the majority of personnel exposed in this manner. Two home-related incidents, involving 9 children under the age of 16 (one of which died) and one adult, were also reported. These two home-related incidents were clearly a misuse since the user disregarded the label instructions. The other incidents were attributed to accidental pesticide spills or were of undetermined origin. In all of these incidents, exposure to aluminum phosphide or phosphine occurred through improper handling of the pesticide (not wearing required protective clothing), incomplete aeration procedures (i.e., not determining phosphine levels prior to reentry or not wearing the required respirator), or improper rates of application of the pesticide to the commodities.

In the literature, 12 studies dating from 1936 to 1980, reported case histories of human exposure to phosphine gas. A total of 129 persons were exposed to the gas in varying situations. These studies have described gastrointestinal disorders which included vomiting and diarrhea, and nausea as the most prevalent symptoms. Headache, dizziness and breathing difficulties were also noted. In the survivors, recovery times ranged from 24 hours to 1 month following exposure. Autopsy findings indicated that pulmonary edema and congestive heart failure were the most frequent causes of death from phosphine gas exposure.

One of these studies (Zipf et al., 1967, MRID #005017653) which addressed a suicide attempt with Phostoxin® provided a description of medical treatment following aluminum phosphide poisoning. The authors recommended a rapid and thorough stomach evacuation irrigation, irrigation with 1% potassium permanganate solution or magnesium peroxide and treatment with activated charcoal and sodium sulfate. Thereafter, immediate administration of oxygen,

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* The Agency will accept the data being requested under the Aluminum Phosphide Registration Standard (EPA, 1981) to support the registration/reregistration of products containing magnesium phosphide.

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they indicated, will help to prevent death from circulatory system collapse and pulmonary edema. When renal insufficiency is present, extracorporeal hemodialysis proved effective.

E. Permissible Exposure Limits

The American Conference of Industrial Hygienists (ACIH, 1971) has established a normal allowable occupational exposure limit (TLV) of 0.3 ppm for phosphine based on acute and subchronic inhalation studies. This has also been adopted by National Institute of Occupational Safety and Health (NIOSH, 1979) and Occupational Safety and Health Administration (NIOSH/OSHA, 1978) as a permissible exposure limit (PEL). Both the TLV and the PEL represent time weighted averages of airborne concentrations which should not cause harm to workers exposed eight hours per day, five days per week throughout a working lifetime.

Because the Agency is concerned about adverse chronic effects, other than overt symptoms and lethality, we reserve the decision to require some studies, such as mutagenicity and teratology, until the results of reentry data can be evaluated. If there is significant chronic exposure to the applicator based on this review, the Agency may require these studies.

F. Food Tolerances

Considering that phosphine is a gas and thus only low levels of phosphine residues are expected in treated food commodities, it is anticipated that the public which consumes phosphine-treated food commodities will be exposed to toxicologically insignificant quantities of phosphine per se (see Part VII, Residue Chemistry). As no significant dietary exposure to phosphine is expected, no chronic feeding, oncogenic, metabolism or reproduction studies are required for phosphine.

However, chemically uncharacterized residues are found in food commodities as a result of phosphine treatment (see Part VII, Residue Chemistry). There is a chronic feeding/oncogenic study (Hackenberg, 1969, MRID #000026937; 1971, MRID #000026938; 1972, MRID #000006000) in which rats were fed a phosphine-treated diet and were presumably exposed to levels of chemically uncharacterized residues which result from phosphine treatment. The Hackenberg study is an inadequate measure of the possible hazards arising from the consumption of these residues. The levels of this chemically uncharacterized substance are unknown and are very likely below the maximum tolerated dose. Therefore, the study, at best, is very insensitive. Nevertheless, it provides no evidence that any harm will result from consumption of phosphine-treated food commodities. It is therefore reasonable to defer the requirement for chronic feeding, oncogenic, metabolism and reproduction studies pending a determination of the chemical nature of the chemically uncharacterized residues.

If the Agency concludes, when these residues are chemically characterized, that they are toxicologically insignificant, the requirement for chronic feeding, oncogenic, metabolism, and reproduction studies will be waived. If no determination can be made, chronic feeding, oncogenic, metabolism, and reproduction studies may be required. Therefore, the requirement for these studies is being deferred until the residues are chemically characterized, and the Agency reviews the results*.

G. Summary of Data Gaps

All required toxicology studies are reserved pending the receipt and evalution of residue and reentry data. When the chemically uncharacterized residues which result from the treatment of food commodities with phosphine are characterized and evaluated, the Agency will determine whether chronic feeding/oncogenic, metabolism and reproduction studies are required. When the reentry data are received and evaluated to determine if there is any exposure to the applicator, the Agency will determine whether mutagenicity, teratology and additional subchronic inhalation studies are required.

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* The Agency will accept the data generated under the Aluminum Phosphide Registration Standard (EPA, 1931) to support the registration/reregistration of products containing magnesium phosphide.

VII. Residue Chemistry

A. Introduction

Products of both aluminum phosphide and magnesium phosphide are used primarily as a source of the fumigant phosphine. Both types of products are currently registered with directions for blending directly with raw agricultural commodities, and as space fumigants for processed foods, feeds, non-food items such as tobacco stored in commerial establishments. Recently, both types of products were accepted for use as rodenticides. When these products are used as space fumigants, the resulting residues are limited to phosphine per se and its reaction products with the commodity. However, when mixed with raw agricultural commodities, the residues also include small amounts of the product which are impregnated with magnesium phosphide.

As with aluminum phosphide, the recommended application rates for magnesium phosphide vary with the nature of the pest and the tightness of the structure (e.g., bin, warehouse, railcar). To effectively fumigate with phosphine, the commodity should be at a temperature ≥ 40°F (4.4°C) and the humidity about 60%. A detailed summary of the accepted application rates for magnesium phosphide can be found in the EPA Index to Pesticide Chemicals-Magnesium Phosphide (EPA, 1981). In brief, the application rates of magnesium phosphide products are as follows: 1) when mixed with the commodity, application rates of magnesium phosphide range between 4 and 12 grams per ton of commodity (or 48 to 360 grams per 1,000 bushels) and 2) when not mixed with the commodity, application rates are between 60 grams and 250 grams of phosphine per 1,000 cubic feet of volume fumigated (or 2.12 mgs and 8.83 mgs per liter).

As products for fumigation, the phosphides of magnesium and aluminum have been accepted for essentially the same uses. Both types of products are used to fumigate raw agricultural commodities (e.g., wheat), processed foods and feeds, empty beehives, nonfood items (e.g., tobacco, seeds), and commercial establishments (e.g., cereal mills).

B. Fumigation and Aeration Periods

The length of the fumigation period is dependent upon the temperature of the commodity. Commodities at 54-59°F (12.2-15°C) should be fumigated at least four days. If the commodity is between 60-68°F (15.6-20°C), the time should be at least three days; if over 68°F (20°C), the time must be not less than two days. No fumigation should be made at tempeartures below 40°F (4.4°C). The aeration period following fumigation should be at least two days.

C. Metabolism in Plants and Animals

Data reviewed for the Aluminum Phosphide Registration Standard (EPA, 1981) show that the highest residues of phosphine occur when the product has been mixed directly with the fumigated commodity. These residues resulted because small amounts of unreacted phosphide remain with the product non-volatiles. In registering products formulated with the phosphides of either aluminum or magnesium, the Agency has not required residue data individually for each product; the Agency assumed that residues of such unreacted phosphide are not significantly dependent upon the formulation of the end-use product.

The reviewed submissions for magnesium phosphide, including those for the phosphides of aluminum and zinc, do not contain data showing the plant metabolites of phosphine *per se*. These submissions, which support the currently established tolerances for residues resulting from fumigations with phosphide, indicate only minute (>0.01 ppm) residues of phosphine *per se* (which were readily removed by aeration) and the Agency does not require either plant of animal metabolism studies at this time.

However, based on recent studies conducted with ^{32}P-labeled phosphine and nuclear activation studies using unlabeled phosphine, the Agency requested for the Aluminum Phosphide Registration Standard (EPA, 19931) data which would identify phosphine residues which were not indicated by earlier studies using less sophisticated methodology. The requested data, which is also needed to support the magnesium phosphide standard, may indicate the need for metabolism studies.

The more recent studies indicate about 70% of the irreversibly bound residue of phosphine consists of the oxy-acids of phosphorus (phosphoric, phosphorus, and hypophophosphorus), the amount of the residue remaining unidentifed in these studies was significant. For example, in a typical phosphine fumigation of wheat, the unidentified residue consists of about 30% of the total ^{32}P-residue, about 0.7 ppm. The Agency, therefore, has requested that the remaining residue be identified and recognized as safe or studied in accordance with the Agency's Guideline requirements.

D. Analytical Methods

The current Pesticide Analytical Manual (PAM), 1981, Vol II, contains the official analytical procedure for enforcing the established tolerances for residues of phosphine in or on raw agricultural commodities, processed foods and feeds. Currently, the methodology is considered valid for phosphine residues which are $\geq$ 0.01 ppm.

E. Residue Data

Sufficient data have been submitted to show that the phosphine release rate from the registered magnesium and aluminum phosphide products are not significantly different (DEGESCH, America, Inc., 1977, MRID #GS0097002). Because the two phosphides have essentially the same uses, the residue data supporting the aluminum phosphide products are considered valid for products of magnesium phosphide. [Note: The carryover of significant amounts of residue, either of phosphine *per se* or of magnesium phosphide (or aluminum phosphide) into processed commodities and into meat, milk, poultry and eggs would not be expected.]

F. Summary of Data Gaps

As discussed in Section C, Metabolism by Plants and Animals, phosphine reacts irreversibly with treated commodities. Grain fumigation studies conducted with ^{32}P-phosphine indicate these irreversibly bound residues consisted of both the oxy-acids of phosphorus (≤2.5 ppm) and unidentified residues (ca 0.7 ppm). These studies also indicated that the same or similar residues, in about the same quantities, are present in all commodities fumigated with phosphine. Thus, in order to evaluate the hazards that would be associated with the use of magnesium phosphide, the Agency is requiring that these unidentified residues of phosphine be either identified chemically and recognized as safe, or tested in accordance with the Agency's Guidelines*.

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* The Agency will accept the data generated under the Aluminum Phosphide Registration Standard (EPA, 1981) to support the registration/reregistration of products containing magnesium phosphide.

VIII. Ecological Effects

Subpart E, Hazard Evaluation: "Wildlife and Aquatic Organisms," of the Proposed Guidelines issued on July 10, 1978, describes the fish and wildlife data requirements needed by the Agency to assess the hazards of pesticides to nontarget organisms and to provide for adequate precautionary labeling. There are no fish and wildlife toxicity studies on magnesium phosphide. However, such data will not be required to support the use patterns covered by this standard because 1) magnesium phosphide, in the presence of moisture, decomposes rapidly to produce phosphine gas; 2) the treatment sites for the insecticide use are enclosed or covered during treatment, thereby precluding exposure to fish and wildlife; and 3) the residual phosphine will be diluted upon release into the surrounding air when venting a treated area. Thus, the Agency will waive the ecological effects data requirements regarding the currently registered uses (i.e., the fumigation of foods, feeds, processed foods and feeds in enclosed structures, and the fumigation of rodent burrows) for magnesium phosphide products.

The use patterns of magnesium phosphide for controlling burrowing rodents and moles could destroy nontarget mammalian, avian, and reptilian species that prey on these pests or are utilizing their burrows at the time of application. The following endangered species were determined to be in jeopardy through the use of this product*: 1) Black-footed ferret (Mustela nigripes); 2) Eastern Indigo snake (Drymarchon corais cauperi); 3) San Joaquin kit fox (Vulpes macrotis mutica); 4) Utah prairie dogs (Cynomys parvidens); 5) Blunt-nosed leopard lizard (Gamelia: Crotaphytus); and 6) Desert tortoise (Gopherus agassizii). The Agency has required labeling changes for products covered by this Standard to reduce and/or eliminate potential hazards to nontarget organisms; i.e., endangered species (see Part II).

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* These species were determined through formal Section 7 consultation with the Office of Endangered Species, U.S. Fish and Wildlife Service.

IX. Confidential Annex

Persons wishing to read the contents of this annex, which contains Confidential Business Information, are requested to contact the United States Environmental Protection Agency, Office of Pesticide Programs, Information Services Branch (Freedom of Information), for further details.

X. Bibliography

A. Guide to Use of This Bibliography

1. Content of Bibliography

This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this Standard. The bibliography is divided into 3 sections: 1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the Standard; 2) citations examined and judged to be inappropriate for use in developing the Standard; and 3) standard reference material. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry

The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries on them, treating them as a single study.

3. Identification of Entries

The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, a nine-digit identifier. This number is unique to the citation, and should be used at any time specific reference is required. This number is called the "Master Record Identifier," or "MRID." It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data (see paragraph 4(d)(4) below for further explanation).

4. Form of the Entry

In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by description of the earliest known submission. The bibliographic conventions used reflect the standards for the American National Standards Institute (ANSI) and was expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

a. Author

Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

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b. Document Date

When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title

This is the third element in the citation. In some cases it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between brackets.

d. Trailing Parentheses

This is the third element in the citation. In some cases it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between brackets.

e. Trailing Parentheses

For studies submitted to us in the past, the following elements describing the earliest known submission (in addition to any self-explanatory text) are included within the trailing parentheses.

1) Submission Date. Immediately following the word "received" appears the date of the earliest known submission.

2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

3) Submitter. The third element is the submitter, fol lowing the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

4) Volume Identification. The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th,123456-Z and the 27th 123456-AA.

MAGNESIUM PHOSPHIDE BIBLIOGRAPHY
Section 1

Citations Considered To Be Part Of The Data Base Supporting
Registration Under The Standard

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Standard

Product Chemistry (Part IV)

MRID #	Citation
GS0097007	DEGESCH America, Incorporated (197?) DEGESCH Magtoxin Pellets. (Unpublished study received on unknown date under 40285-10)
GS0097008	DEGESCH America, Incorporated (197?) DEGESCH Magtoxin Pellets (Unpublished study received on unknown date under 40285-11)
GS0097006	DEGESCH America, Incorporated (197?) Fumi-Cel® Plate. (Unpublished study received on unknown date under 40285-8)
GS0097009	DEGESCH America, Incorporated (197?) Magtoxin Pellets Prepac (Unpublished study received on unknown date under 40285-12)
GS0097002	DEGESCH America, Incorporated (1977) Phostoxin (Unpublished study received June 13, 1977 under unknown submission; CDL:234589)
000005669	Dittmar (1960) Examinations for Testing of the Phostoxin Method Regarding Fire and Explosion Safety. (English translation; unpublished study received Aug 25, 1960 under 5857-1; prepared by Bundesanstalt fuer Materialpruefung for Deutsche Gesellschaft fuer Schaedlingsbekaempfung m.b.H., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:022500-A)
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MRID #	Citation
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MRID #	Citation
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